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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,724	09/22/2000	Pramod K. Srivastava	8449-128-999	1804

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NEW YORK, NY 100362711

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/668,724

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31,32,71 and 75-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31,32,71 and 75-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The amendment filed 11/7/2002 (paper no. 14) is acknowledged and entered into the record. Accordingly, claims 31 and 71 are amended and claims 85-91 are newly added.
2. Claims 31-32, 71, and 75-91 are pending and examined on the record.

### ***Inventorship***

3. In view of the papers filed 8/13/2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Robert J. Binder.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

### ***Information Disclosure Statement***

4. The Information Disclosure Statement filed 11/7/2002 (paper no. 15) is acknowledged and considered. A signed copy of the IDS is attached hereto.

### ***New Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

5. Claims 31-32, 71, 75-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW

MATTER REJECTION. Claims are drawn to a method of modulating an immune response with a compound wherein the compound inhibits the interaction of an HSP with an  $\alpha$ 2MR, wherein the compound is other than and HSP, a complex of HSP and a peptide, RAP,  $\alpha$ 2M or a complex of  $\alpha$ 2M and a peptide. Applicant directs the examiner to page 12 line 13-20 for support of the newly added limitations to the claims. However, there is no proviso language so as to exclude an HSP, a complex of HSP and a peptide, RAP,  $\alpha$ 2M or a complex of  $\alpha$ 2M and a peptide as the desired compound. Instead, the specification further expands the choices of compounds that can be used to accomplish the desired effect of the method. Therefore, applicant must remove any limitation that excludes such compounds from the claim.

***Specification***

6. The amendment filed 11/7/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the exclusion of an HSP, a complex of HSP and a peptide, RAP,  $\alpha$ 2M or a complex of  $\alpha$ 2M and a peptide as the compound which is able to modulate the interaction of a first HSP with  $\alpha$ 2MR.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections Withdrawn - 35 USC § 112, 2<sup>nd</sup> paragraph***

7. The rejection of claims 31,32,71 and 75-84 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn in view of the amendments to the claims and the persuasive arguments presented by the applicant.

***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

8. The rejection of claims 31,32,71,75, and 77-84 under 35 USC 112,1<sup>st</sup> paragraph as lacking an enabling disclosure is **withdrawn in part**, wherein the rejection of claims 31,76,77, and 79-82 are withdrawn in view of the amendments to the claims set forth by the applicant. Claims 32, 71, 78, and 83-84 and newly added claims 85-91 are rejected (see below for response to amendment).

***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

9. The rejection of claims 75 and 76 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is withdrawn in view of the persuasive arguments presented by the applicant.

***Claim Rejections Maintained- 35 USC § 112, 1<sup>st</sup> paragraph***

10. The rejection of claims 32, 71, 78, and 83-84 and newly added claims 85-91 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instant specification provides ample teaching so as to enable one of skill in the art to practice the instant invention. Applicant argues that the specification enables the artisan not only to measure direct binding or activation of the  $\alpha$ 2MR, but also increases in receptor activity or intracellular signaling events, wherein the intracellular activity could be the release of calcium stores or the release of cytokines. Applicant further argues that because the specification provides methods of how to assay for these agonists or compounds that enhance receptor activity, that the actual identity of the agonist or compound itself is not needed because the skilled artisan could easily test for such compounds from a list of potential

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compounds taught in the specification. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The claims are drawn to a method of modulating an immune response comprising the administration of a compound that is an agonist capable of enhancing the interaction of the HSP with a2MR. Because the invention claims a compound that is capable of increasing the interaction between two proteins, this would imply that the compound increases binding affinity between two proteins, and not necessarily receptor activity. Although it is understood by the examiner that receptor activity can be measured through various methods, the compound that is capable of increasing the affinity between HSPs and a2MR needs to be known in order for the skilled artisan to practice the recited invention. The skilled artisan would find it difficult to practice the invention without knowing the actual identity of agonist because the specification has only provided desired embodiments and has not taught which specific compounds are capable of producing an increase or enhancement of HSP- a2MR binding interactions. Therefore, in order for the skilled artisan to practice the invention, they would need to assay for and test various forms of compounds ranging from peptides, antibodies, inorganic molecules, and organic molecules. Although routine experimentation is acceptable, this type of testing or screening would require undue experimentation because the skilled artisan is essentially required to discover or define a compound from a multitude of potential candidates.

***Claim Rejections Maintained - 35 USC § 102***

11. The rejection of claims 71, 76, 83, and 84 under 35 USC 102(b) as being anticipated by Pizzo *et al* (IDS CT) is maintained for the reasons of record. Applicant argues that the amendment to the claims obviate the rejection and further argues that the removal of a species so as to render the claims unanticipated by the prior art is supported by *In re Johnson*, 194 U.S.P.Q. 187 (C.C.P.A. 1977). Applicant's arguments have been carefully considered but are not found persuasive for the following reason. The removal of a species from the claim under *In re Johnson* if and only there is support in the specification for the removal of the species. In the instant case, there is no support in the specification for a negative limitation so as to exclude an HSP, a complex of HSP and a peptide, RAP,  $\alpha$ 2M or a complex of  $\alpha$ 2M and a peptide so that the prior art can be obviated. As such, the claims are still anticipated by Pizzo *et al*.

***New Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

12. Claims 31-32, 71, and 75-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Regarding claims 31 and dependent claims thereof, in the recitation of the term "decrease", it is a relative term that must be compared to a control level, of which there is not recitation in the claim.

14. Regarding claims 31 and dependent claims thereof, in the recitation of the "amount effective" it is unclear from the specification the amount intended to be

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administered so as to be "effective". The claim is therefore indefinite and the metes and bounds cannot be determined.

15. Regarding claim 31 and dependent claims thereof, in the recitation of the term "modulate" as it is newly amended (i.e. "to modulate the immune response..."), it is unclear how a decrease in the interaction of an HSP with an  $\alpha$ 2MR would result in the modulation of an immune response.

### ***Conclusion***

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
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February 23, 2003

*Ali R. Salimi*  
PRIMARY EXAMINER  
ALI R. SALIMI